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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/729,768 | 12/05/2003 | Peter M. Bonutti | 2500DV2CN2DV3CN5 | 3380 |

7590 03/03/2006

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Norwalk, CT 06856

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| EXAMINER |
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THALER, MICHAEL H

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| ART UNIT | PAPER NUMBER |
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3731

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 10/729,768 | | BONUTTI, PETER M. | |
| | Examiner | | Art Unit | |
| | Michael Thaler | | 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-20 and 23-25 is/are pending in the application.
- 4a) Of the above claim(s) 23-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Claims 23-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on Feb. 18, 2005.

Claims 15-20 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sheldon (3,417,745). Sheldon, in figure 3, discloses shaft 56 and inflatable bladder 57 which has an eccentric shape upon inflation and cannula 5. Alternatively, the inflatable bladder 57 in figure 4 has the shape of a wedge since it tapers in the proximal direction. The Sheldon bladder, when inflated and axially moved with respect to the cannula, is inherently capable of separating adjacent layers of tissue since the bladder is made of the very strong inelastic material of Mylar (col. 8, lines 55-58) and is filled with a substantially non-compressible material which is liquid (the fluid in the phrase "fluid or gas" referred to in col. 8, line 68) which is substantially non-compressible. Alternatively, it would have been obvious that the Sheldon device creates a working space for the reasons set forth above. Cannula 5 has a passage "therethrough" when it is expanded as described in col. 3, lines 19-36. As to claim 16, Mylar (col. 8, lines 55-58) does not

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stretch when fully inflated. As to claim 19, shaft 56 is rigidified when attached to rigid shaft 2 (col. 2, lines 39-40 and 60-63).

Claims 15-20 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Froning (3,875,595). Froning discloses shaft 47, 48, inflatable bladder 46 which has an eccentric shape upon inflation (since the portion on one side of the longitudinal axis of shaft 47, 48 is larger than the portion on the other side of the longitudinal axis) and cannula 31. The Froning bladder, when inflated and axially moved with respect to the cannula, is inherently capable of separating adjacent layers of tissue since the bladder is made of material which is sufficiently strong to hold fluid under pressure (col. 3, lines 17-21) and is filled with a substantially non-compressible material (the water described in col. 3, lines 17-21). Alternatively, it would have been obvious that the Froning device is capable of creating a working space for the reasons set forth above. As to claim 16, stretching of bladder 46 will be finished when it is fully inflated. As to claim 19, portion 48 of the shaft is rigid.

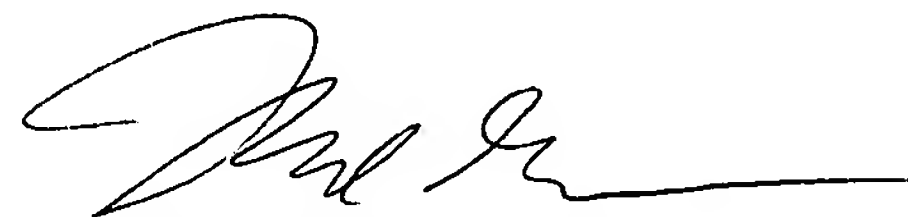
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Applicant's arguments filed Jan. 23, 2006 have been fully considered but they are not persuasive for the reasons set forth above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (571)272-4704. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

mht
2/27/06



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731